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| Goodwin Procter LLP Attn: Patent Administrator 135 Commonwealth Drive Menlo Park, CA 94025-1105 | | | EXAMINER SZMAL, BRIAN SCOTT | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/574,373

Applicant(s)

BOECKER, DIRK

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 31 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GC/8)
Paper No(s)/Mail Date See Continuation Sheet
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/17/09; 12/8/09; 1/20/10; 3/5/10; 9/9/10.

Claim Objections

1. Claim 8 is objected to because of the following informalities: The claim does not have a "." at the end of the claim. Appropriate correction is required.
2. Claims 16 and 19 are objected to because of the following informalities: "users" should read as "user's". Appropriate correction is required.
3. Claim 18 is objected to because of the following informalities: "your email account" should read as "an email account". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 2-5 and 8-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 3 and 4, the claims disclose a wireless device that allows "programs to be downloaded to the processor". It is unclear to the Examiner how a computer program can be downloaded to a processor, since the processor does not have any memory for storing computer programs. Furthermore, amended claims 2-5 and 8 incorporate "the processor having instructions". It is unclear how a processor would have instructions, since processors only process data and run computer programs. In order to have a device that has a processor, the device must also have a memory for storing at least one computer program to operate the device. Therefore, it is

unclear how a processor would have instructions stored therein, since a processor does not store computer programs.

6. Claim 5 recites the limitation "the penetrating member driver" in line 8. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 12 discloses the use of the 1394 IEEE protocol. The 1394 IEEE protocol was first introduced in 1995 as IEEE Std. 1394-1995, then the IEEE Std. 1394-1995 was amended in 2000, 2002 and 2006 to become IEEE Std. 1394a-2000 amendment, the IEEE Std. 1394b-2002 amendment, and the IEEE Std. 1394c-2006 amendment, respectively. On June 12, 2008, all these amendments as well as errata and some technical updates were incorporated into a superseding standard IEEE Std. 1394-2008. It is unclear to the Examiner exactly which 1394 IEEE protocol the Applicants are attempting to claim.

8. Claim 12 contains the trademark/trade name Bluetooth. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a wireless transmission protocol and, accordingly, the identification/description is indefinite.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 2-5 and 8-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2-5 and 8 have been amended to incorporate the limitation "the processor having instructions...for determining that a penetrating member has contacted a skin surface". The current specification fails to support this limitation.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bylund et al (2003/0212379 A1) in view of Aceti et al (2003/0153900 A1) in view of Sahay et al (4,442,972).

Bylund et al disclose a means for monitoring analytes and further disclose a housing; a penetrating member in the housing; a display in the housing; a processor

driving the display, wherein the processor runs software that is modifiable to provide a variable user interface on the visual display; and a series of buttons on the housing for changing lancing settings shown on the display (the buttons on the housing can be used to turn the device on and off, thereby controlling the lancing settings). See whole document, in particular, Paragraphs 0070-0073.

Bylund et al however fail to disclose a plurality of penetrating members; a processor for controlling the penetrating member driver; and a wireless communication device allowing programs to be downloaded to the device by wireless communications.

Aceti et al, as discussed above, disclose an automatic means for obtaining fluid for analyte analysis and further disclose a plurality of penetrating members; a processor for controlling the penetrating member driver; and a wireless communication device (PDA) allowing programs to be downloaded to the device by wireless communications. See Figures 1, 3, 5-7 and 27; and Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Bylund et al to use a plurality of penetrating members, a processor to operate the driver and a wireless communication device for downloading programs wirelessly, as per the teachings of Aceti et al, since it would provide an automatic and programmable means for penetrating the skin and obtaining a fluid sample.

Bylund et al and Aceti et al however fail to disclose the display having at least one visual indicator positioned next to a corresponding marking on the housing.

Sahay et al, as discussed above, disclose a programmable digital thermostat and further disclose the display having at least one visual indicator positioned next to a corresponding marking on the housing. See Figure 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Bylund et al and Aceti et al to include corresponding indicators on the housing adjacent to the visual indicator, as per the teachings of Sahay et al, since it would provide a means of displaying information on the device without requiring a large display.

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al (2004/0176705 A1) in view of Aceti et al (2003/0153900 A1) in view of Luna et al (2002/0123335 A1).

Stevens et al disclose a integrated lancet and PDA system and further disclose a housing; penetrating members positioned in the housing; an analyte detecting member coupled to the sample chamber, the analyte detecting member being configured to determine a concentration of an analyte in a body fluid; a visual display on the housing; a processor driving the visual display, the processor runs software that is modifiable to provide a variable user interface on the visual display; and a wireless communication device allowing programs to be downloaded to the processor by wireless communication. See Paragraphs 0012, 0024-0026, 0028, 0029, 0032 and 0038.

Stevens et al however fail to disclose a plurality of penetrating members, and a driver coupled to the penetrating members; and using a sample size of less than 1 μ L.

Aceti et al disclose an ambulatory analyte monitor and further disclose a plurality of penetrating member sin the housing; a penetrating member driver coupled to the penetrating members; and the analyte detecting member being configured to determine a concentration of an analyte in a body fluid using a sample of less than 1 μ L of a body fluid disposed in the sample chamber; a visual display on the housing. See Paragraphs 0104, 0106, 0137, 0143 and 0163; and Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Stevens et al to include the use of a plurality of penetrating members and a sample size of less than 1 μ L, as per the teachings of Aceti et al, since a smaller sample size requires less time to measure the analyte concentration while being less painful to the user.

Stevens et al and Aceti et al however fail to disclose the use of a screensaver on the display.

Luna et al discloses the use of a screensaver on a computer. See Paragraph 0027.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Stevens et al and Aceti et al to include the use of a screensaver, as per the teachings of Luna et al, since it is well known to utilize screensavers on computer devices to protect the screen while the device is not in use.

14. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al (2003/0153900 A1) in view of Britt, Jr. (2001/0037355 A1).

Aceti et al, as discussed above, disclose an analyte monitor, and further disclose the analyte monitor is a handheld device. See at least Figure 27.

Aceti et al however fail to disclose downloading software to the device.

Britt, Jr. discloses a system that allows the device to download software. See Paragraphs 0026-0028.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Aceti et al to include the ability to download software, as per the teachings of Britt, Jr. since it is well known that networked devices have the ability to download and upload information through a network.

15. Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bylund et al (2003/0212379 A1) in view of Aceti et al (2003/0153900 A1) in view of Ware et al (2002/0019747 A1).

Bylund et al, as discussed above, disclose an analyte monitoring means and further disclose a housing; a display on the housing; a penetrating member in the housing; a processor driving the display; and a variable user interface on the display; the monitor includes a keyboard on the housing; and the use of audio alerts, visual alerts or email alerts to an email account due to missing a certain number of testing events. See whole document, in particular, Paragraphs 0069-0073.

Bylund et al however fail to disclose a plurality of penetrating members in the housing; a penetrating member driver; a processor for controlling the penetrating member driver.

Aceti et al, as discussed above, disclose an analyte monitor and further disclose a plurality of penetrating members in the housing; a penetrating member driver; a processor for controlling the penetrating member driver. See Paragraphs 0104, 0106, 0137, 0143 and 0163.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Bylund et al to provide a plurality of penetrating members, a driver to operate the penetrating members, and a processor to control the driver, as per the teachings of Aceti et al, since it would provide an automatic and programmable means for penetrating the skin and obtaining a fluid sample.

Bylund et al and Aceti et al, however, fail to disclose answering a plurality of questions, analyzing the responses to the questions, downloading programs, the questions are from a personality test, the answers are transmitted to the server for analysis, the answers are transmitted wirelessly using infrared; the updates are automatically downloaded after a period of time; the user enters a code to determine the type of user interface to be displayed; upgrading the user interface to a new one matching or suited for the user's age after a set period of time, yearly or on the user's birthday; alerting the user after a certain number of missed events; and email the result to an email account.

Ware et al disclose a means for health assessment and monitoring and further disclose answering a plurality of questions, analyzing the responses to the questions, downloading programs, the questions are from a personality test, the answers are transmitted to the server for analysis, the answers are transmitted wirelessly using

infrared; the updates are automatically downloaded after a period of time; the user enters a code to determine the type of user interface to be displayed; upgrading the user interface to a new one matching or suited for the user's age after a set period of time, yearly or on the user's birthday; alerting the user after a certain number of missed events; and email the result to an email account. See Figures 7-1 through 7-10 and 8-1 through 8-28; Paragraph 0067, 0113, 0114, 0141 and 0143.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Bylund et al and Aceti et al to include the ability to provide a list of questions and transmit the answers to a remote server, as per the teachings of Ware et al, since it is well known in the art to utilize networks, including wireless connections, to transmit data to and from computers as well as using remote sites to analyze data obtained from the local site.

Response to Arguments

16. Applicant's arguments with respect to claims 2-5 and 8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736